

REMARKS

In view of the foregoing amendments and the following representations, reconsideration and allowance of the above-identified application is respectfully requested.

Claims 1-12, 15, 16 and 19-23, 29 and 30 are pending in the present application.

New claims 29 and 30 are added by the present amendment. Claim 29 is limited to a bilayer omeprazole tablet and claim 30 is limited to a trilayer omeprazole tablet. No new matter is added by these amendments. Support can be found in the claims as originally filed and in the Examples on pages 14-28. More specifically, Examples 1-3 and 5-6 disclose bilayered omeprazole tablets and Examples 4, 9, and 10 disclose trilayered omeprazole tablets.

In the September 23, 2008 Office Action, the Examiner maintained the rejection of claims 1-12, 15, 16 and 19-23 under 35 U.S.C. § 103(a) as being unpatentable over Phillips, United States Patent No. 6,645,988 (hereinafter "Phillips") in view of Shimizu et al., United States Patent No. 6,328,994 ("Shimizu").

The Examiner stated on pages 2-3 of the Office Action:

Applicants' remarks regarding the combination of the two reference does not teach the instant multi-layered pharmaceutical dosage form composition with a film forming water insoluble polymer are not persuasive since the applicants' examples contain ethylcellulose and HPMC (hydroxypropylmethyl cellulose) in various compositions (See Examples 11-13). Are the polymers (water-soluble or water insoluble)?

In response to this inquiry, Applicants admit that HPMC is a water soluble film forming polymer and ethylcellulose is a water insoluble film forming polymer. To further

support this admission, attached hereto as Exhibit A are pages 237-241 and 297-300 of the *Handbook of Pharmaceutical Excipients*, 4th ed. Pages 237-241 are the monograph for ethylcellulose and indicate that ethylcellulose is **insoluble in water** but soluble in certain organic solvents. Pages 297-300 are the monograph for HPMC and indicate HPMC is **soluble in water** but insoluble in certain organic solvents. The HPMC monograph is consistent with the teachings on Col. 13, lines 1-8 of Shimizu which the Examiner relied upon in the prior rejections.

Applicants respectfully submit that a skilled artisan would understand that the present claims require a proton pump inhibitor granule that employs a **water insoluble** film forming polymer or a congeable material. This understanding is based upon the examples and the use of the term “comprising” in the pending claims when describing the proton pump inhibitor granules (claim 1) or the omeprazole granules (claims 29-30). Applicant have discovered the use of the water insoluble polymer and/or congeable material to prepare proton pump inhibitor granules in conjunction with the recited antacid layers surprisingly allows for the elimination of enteric materials.

Based upon the clarification of the solubilities for ethylcellulose and HPMC, Applicants respectfully request reconsideration of the rejection of claims 1-12, 15, 16 and 19-23. As explained in detail in the June 13, 2008 Amendment, all the pending claims recite a multi-layered dosage form comprising (a) a proton pump inhibitor layer and (b) an antacid layer wherein the proton pump inhibitor layer comprises a proton pump inhibitor granule and a pharmaceutical excipient. The proton pump inhibitor granule comprises (i) a proton pump inhibitor and (ii) a water insoluble film forming polymer, a

congeable solid material or a mixture of a water insoluble film forming polymer and a congeable solid material. All pending claims also require the dosage form to be free of acidic film forming polymers, enteric polymers and sodium bicarbonate.

Neither Phillip or Shimizu disclose or suggest the multi-layered dosage form as recited in the pending claims that is free of enteric polymers, free of sodium bicarbonate and employs a novel proton pump inhibitor granule prepared with a water insoluble film forming polymer or a congeable material. Applicants further submit neither reference discloses or suggests a multi-layered dosage form that employs a wax, glyceryl monostearate or castor oil as recited in dependent claims 15 and 16.

Phillips describes a wide range of potential dosage forms on Col. 14, lines 9-16 but fails to provide any disclosure that would lead an individual of ordinary skill to employ a water insoluble film forming polymer or a congeable solid material in preparation of a proton pump inhibitor granule. The only description of possible excipients appears on Col. 14, lines 24-46 of Phillips. This portion of Phillips does not mention water insoluble film forming polymers or congeable solid materials as required by the pending claims.

As explained in the prior submissions Shimizu only teaches proton pump inhibitor granules comprising water soluble polymers. Shimizu does not teach or suggests a multi-layered dosage form comprising proton pump inhibitor granules prepared with a water insoluble film forming polymer or congeable material and that is free of enteric materials as recited in the pending claims.

Applicants also respectfully submit neither Phillip alone or combined with Shimizu would lead a skilled artisan to the bilayered omeprazole/antacid tablet recited

in claim 29 which employs an omeprazole granule comprising a water insoluble film forming polymer or congeable material and that is free of sodium bicarbonate and enteric material. Similarly neither Phillip alone or combined with Shimizu would lead a skilled artisan to the trilayered omeprazole/antacid tablet recited in claim 30 which employs an omeprazole granule comprising a water insoluble film forming polymer or congeable material and is free of sodium bicarbonate and enteric material. Phillip and Shimizu would only suggest to a skilled artisan a tablet that employs water soluble materials, sodium bicarbonate and enteric materials.

Based upon the foregoing amendments and representations, Applicants respectfully submit that the rejection of the claims in the above-identified application have been overcome and should be withdrawn. Early and favorable action is earnestly solicited.

Respectfully submitted,

A large, stylized handwritten signature in black ink, appearing to read 'M. Endres', is written over the signature line.

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